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The National Professional Society of Pharmacists

December 23, 2002

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 02N-0417

Dear Sir/Madam:

Thank you for the opportunity to comment on the proposed rule to amend the Food and Drug Administration (FDA) patent listing requirements for new drug applications (NDAs) and revise the regulations regarding the effective date of approval for certain abbreviated new drug applications (ANDAs) and 505(b)(2) applications as published in the October 24, 2002 *Federal Register*. The American Pharmaceutical Association (APhA), the national professional society of pharmacists, represents more than 50,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians.

The approval process for prescription drug products is of obvious interest to pharmacists. Pharmacists rely on the FDA for consistent regulation of product safety and efficacy, including the review and approval of generic products. A major advance of the 20th century was the extent to which pharmacists and other health care professionals came to depend on the FDA to regulate the safety of medications, biologics and devices used by patients. The FDA's regulatory processes are of paramount importance and pharmacists rely on FDA regulation to ensure that, among other activities, all products are approved under a consistent process.

The proposed rule, "Application for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug is Invalid or will not be Infringed," would modify the drug approval process, clarifying the types of patents that may be filed and limiting the number of automatic 30-month stays. According to the Administration, these modifications will improve access to generic medications.

APhA appreciates the Administration's and FDA's efforts to increase access to generic medications. Generic medications, which must be comparable to a brand or innovator drug in dosage form, strength, route of administration, quality and performance characteristics,

and intended use, offer health care professionals and their patients with a number of medication alternatives.[1] Pharmacists, as the medication experts on the health care team, inform prescribers and their patients about the availability of generic products, promote the appropriate use of generic medications, and monitor their use.

According to the Administration, the proposed rule will increase access to generic medications by closing "loopholes" in current drug approval law.[2] APhA agrees with the Administration that revisions to existing regulations are necessary to create an appropriate balance between the need to protect innovation and the need for greater accessibility. APhA recognizes the research and development that is required to produce a brand or innovator drug product, and the Association supports patent protections for these products. We also support a system that allows for access to generic alternatives. The proposed rule is a good step in creating a balance between the two.

While APhA supports the proposed rule, we seek clarification, however, with the proposed rule's requirements for patents that may or may not be listed with the FDA. The Agency states that the proposed rule was issued, in part, to help "NDA applicants and NDA holders determine whether specific patents must be submitted to us for listing and to help 505(b)(2) application applicants,"[3] and in response to court decisions on patent issues "which are not entirely consistent with our policies."[4] According to the proposed rule, drug substance (ingredient) patents, drug product (formulation and composition) patents, product by process patents, and method of use patents would be required to be listed with the FDA. Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates would not be allowed to be listed with the FDA.

The proposed rule would require the listing of method of use patents. It is our understanding that method of use patents do not claim the actual approved drug product, but the mechanism of action. APhA is concerned that a method of use patent could prevent other manufacturers from seeking FDA approval for an alternative medication, even if it is a new drug, if the medication relies on the same biological mechanism.[5] If manufacturers are allowed to obtain method of use patents based on the medication's actions through a particular biological pathway, method of use patents could stymie the development of therapeutic alternatives. For example, it appears that method of use patents could have limited the Agency to approving one statin drug or one non-steroidal anti-inflammatory drug because each drug in the class makes use of the same pathway. APhA requests that the Agency reexamine the listing of method of use patents and clarify when it is appropriate for a NDA holder to submit this type of patent.

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[1] Food and Drug Administration. Center for Drug Evaluation and Research. "Overview of ANDA Review Process."

[2] White House Press Release. "President Takes Action to Lower Prescription Drug Prices by Improving Access to Generic Drugs." October 21, 2002.

[3] 67 FR at 65,449

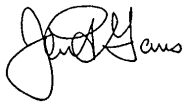
[4] 67 FR at 65,451

[5] 'Use' Patents May Expand Drug Makers' Protection of Intellectual Property. *The Wall Street Journal*. 23 October 2002.

In conclusion, APhA supports the FDA's efforts to make the prescription drug approval more consistent. The proposed rule clarifies several NDA, ANDA, and 505(b)(2) application requirements, and is a good step towards creating a more balanced system between protection of brand patent rights and fair generic competition.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan C. Winckler, APhA's Vice President of Policy and Communications, at 202-429-7533 or SWinckler@APhAnet.org or Susan K. Bishop, APhA's Manager of Regulatory Affairs and Political Action, at 202-429-7538 or SBishop@APhAnet.org with any questions.

Sincerely,



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Susan K. Bishop, Manager, Regulatory Affairs & Political Action